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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,431	06/05/2001	Karl Kolter	51497	5147

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WASHINGTON, DC 20036

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,431

Applicant(s)

KOLTER ET AL

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of amendment B and request for extension of time filed 10/15/02.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-25 under 35 U.S.C. 112, first paragraph, is withdrawn in light of the amendment to the claims.
2. Claims 1-25 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 recite the term “other” in lines 7 and 6 respectively. The term “other” is deemed vague and indefinite because it is not clear what is included or excluded from the term “other” and whether the phrase following said term is indeed a limitation. Applicants may overcome this rejection by deleting the term “other” from the claims.

Although applicants amended claims 10 and 11 by substituting “or” for “and” in both claims, the claims are still vague and confusing because the production process is still both continuous and batchwise. It appears that the production is either continuous or batchwise. Applicants may overcome this rejection by substituting ---either--- for “both” in both claims 10 and 11.

Claim 3 recites the limitation “the combination” in line 3. There is insufficient antecedent basis for this limitation in the claims since claim 1 does not recite “combination.”

Although applicant amended the use claims 24 and 25, the claims are still vague and indefinite because the claims do not have any active method of using.

Claim Rejections - 35 USC § 103

3. Claims 1-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Goertz et al. (US 4,801,460) and Ortega (US 4,837,032) in combination.

Applicants argue that Goertz does not teach a mixture of polyvinyl acetate and polyvinylpyrrolidone to act both as a binder and as a matrix former for the sustained release and that the granulation process of the application does not require the presence of a melt.

4. Applicant's arguments filed 10/15/02 have been fully considered but they are not persuasive.

Applicants' claims do not exclude melt formation and applicants' argument that the prior art fails to show certain features of applicant's invention is not persuasive because it is respectfully noted that the features upon which applicant relies (i.e., a mixture of polyvinyl acetate and polyvinylpyrrolidone act both as a binder and matrix former) are not recited in the rejected claim(s).

Applicants argue that Ortega's process does not include additional solvent and that the processing times of the instant invention are distinctly shorter than that of Ortega and applicants' process avoids the complication of organic solvents using water-sensitive active ingredients.

5. Applicant's arguments filed 10/15/02 have been fully considered but they are not persuasive. Applicants rely on limitations that are not recited in the rejected claim(s).

6. Claims 17-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Noda et al. (US 5,389,380) and Goertz et al. (4,801,460) in combination.

Applicants argue that Goertz requires the complete melting of the polymeric binder and the argument is not persuasive because applicants have not excluded a complete melting of the polymeric binder.

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Applicants argue that the granulation in the invention does not involve melting because the invention does not involve addition of a solvent or binder. The argument is not persuasive because applicants have not excluded the presence of a melt.

In light of the arguments that are presented, applicants state that the combined references do not teach each element of the claimed invention.

In response to the statement that the combined references do not teach each of the elements of the claimed invention, it respectfully noted that applicants argue for limitations that are not claimed in the rejected claims; applicants argue for limitations that are not excluded from applicants invention; applicants argue against the references individually; and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With respect to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Goertz teaches a mixture of polyvinylpyrrolidone and polyvinyl acetate and theophylline (active ingredient) and Noda is relied upon for a teaching of the optional excipients and Ortega is relied upon for the teaching of hydroxypropylcellulose.

No claim is allowed.

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7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

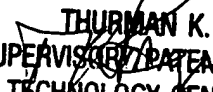
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
January 24, 2003


THURMAN K. PAGE
SUPERVISOR/PATENT EXAMINER
TECHNOLOGY CENTER 1600